



UNITED STATES PATENT AND TRADEMARK OFFICE

indolinone compound, such as sunitinib L-malate, for incorporation in the compositions according to Tang et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 5-8 of the Remarks filed 12 February 2010 that one must make numerous selections in Shenoy et al. in order to arrive at the instant invention, such as selecting the active agent from over 260 compounds, selecting the L-malate salt from a list of possible salts, select the solid formulation even though Shenoy et al. teach that the suspension has higher bioavailability, and selecting the specific component amounts in view of Shenoy et al. teaching extremely broad ranges. Applicants argue that the preferred compounds of Shenoy et al. have vastly different properties than the active being instantly claimed, and thus one of ordinary skill in the art would not be motivated to choose it as the active.

The examiner respectfully argues that Shenoy et al. teach that in a particularly preferred embodiment the indolinone compounds include numerous compounds that are structurally similar to sunitinib and have an amine as opposed to carboxylic acid group (pg. 14). Also, Tang et al. clearly teach sunitinib L-malate as a preferred compound for formulating solid dosage formulations that are very similar to Shenoy et

al. Therefore, one of ordinary skill in the art would reasonably combine the teachings of Shenoy et al. with Tang et al. to arrive at the instant invention.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616